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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,392	08/10/2001	Jae Yong Han	DE1292	8614

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EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,392	HAN ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,4-11,13-25 and 27-39* is/are pending in the application.

4a) Of the above claim(s) *16-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-11,13,14 and 27-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 2, 3, 12 and 26 have been canceled. Claims 27-39 have been added. Claims 1, 4-11, 13-25 and 27-39 are pending.

Election/Restrictions

This application contains claims 16-25 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's arguments filed 10-12-04 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4-11, 13-15 and 27-39 are under consideration in the instant office action.

Priority

The effective filing date of the claimed invention is 2-11-2000, the filing date of PCT/KR00/00104, because 1999-4860, filed in Korea on 2-11-1999, did not teach isolating EG cells as claimed.

Applicants reiterate their belief that claim 1 and Example 1 of the priority document indicate that PGCs are prepared in the first step that inherently comprise EG cells. Therefore, applicants conclude the claim has priority to 2-11-1999. Applicants'

argument is not persuasive. The priority document does not teach that which is essential to the invention. In this case, the priority document does not teach or suggest that the PGCs comprised EG cells. It is not readily apparent that applicants suspected that the method described would result in EG cells (i.e. capable of making a germline chimera upon being introduced into a recipient embryo). The concept of EG cells cannot be found in the priority document. Therefore, the effective filing date of the claimed invention is 2-11-2000.

Claim Rejections - 35 USC § 112

Because the metes and bounds of the claims are unclear (see 112/2nd below), the essential culture methods required to enable one of skill to perform the method claimed cannot be determined. It is noted that, for example, Ponce De Leon (1997, Revista Brasileira de Reproducao Animal, Vol. 21, pg 96-101) taught LIF, bFGF, IGF and SCF are required for long term culture of avian PGCs. If long-term culture is required to make EG cells from PGCs, then an enablement rejection may be required.

Claims 1, 4-11, 13-15 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Culturing PGCs in a medium for a period of time sufficient to obtain EG cell colonies in step a) of claim 1 is described in Example 1, wherein "colonization of EG cells does not occur in the absence of IL-11 and IGF-1."

Culturing EG cells contained in said EG cell colonies in a medium with a feeder layer in step b of claim 1 is found on pg 9, last line, through pg 10, line 14.

Subculturing EG cells of b) in a medium with a feeder layer in step c) is found on pg 10, line 14-19.

Claim 1 remains new matter and claim 29 is new matter.

The range of "stage 14 to 36" in claim 1 cannot be found.

The range of "stage 24 to 30" in claim 29 cannot be found.

The first incubation described in the specification on pg 8, line 34, through pg 9, line 33, did not have a feeder layer as in step a) of claim 1.

The first incubation described in the specification on pg 8, line 34, through pg 9, line 33, did not have a layer of germinal ridge stroma cells (GRSCs) as in step a) of claim 29. In fact, only after the EG cell colonies were established and cultured as described on pg 9, line 36, did applicants obtain EG cell colonies deposited on GRSCs, which is equivalent to step b) of claim 29.

Establishing an "EG cell line consisting essentially of undifferentiated avian cells expressing EG cell characteristics" in claims 1 and 29 cannot be found.

The metes and bounds of what applicants consider "EG cell characteristics" in claims 1 and 29 cannot be found.

Establishing an EG cell line that can "form an embryoid body..." in claims 1 and 29 cannot be found.

Establishing an EG cell line "capable of differentiating into various cell types" in claims 1 and 29 cannot be found.

Establishing an EG cell line capable of producing any "chimera expressing the EG cell phenotype" (in the absence of producing a germline chimera) in claims 1 and 29 cannot be found. A generic chimera that is not a germline chimera is not described in the specification and does not have a disclosed use.

Applicants argue Examples 1 and 2 support the claims as newly amended. Applicants' argument is not persuasive. Examples 1 and 2 are limited to stage 28 chickens (pg 8, line 36), not 14 to 36 as claimed. the other phrases in question could not be found in Examples 1 or 2.

The first incubation described in the specification on pg 8, line 34, through pg 9, line 33, did not have a layer of germinal ridge stroma cells (GRSCs) as in claim 5. In fact, only after the EG cell colonies were established and cultured as described on pg 9, line 36, did applicants obtain EG cell colonies deposited on GRSCs, which correlates to step b) of claim 1 and not step a) as claimed.

The specification does not support using fibroblasts in step b and/or c as newly claimed in claim 13 and new claim 37.

Feeder layers that are "mitotically active" in claim 28 cannot be found.

Claims 1, 4-11 and 13-15 remain rejected and claims 277-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

The rejection regarding the steps of claim 1 has been withdrawn. Step a) requires culturing PGCs with a feeder layer so that EG cell colonies are obtained. Step b) requires culturing the EG cell colonies with a feeder layer so that EG cell colonies are obtained. Step c) require subculturing the EG cells obtained in step b) with a feeder layer so that an EG cell line having an EG cell phenotype is obtained.

The metes and bounds of what applicants consider EG cell colonies cannot be determined (claims 1 and 29) remains unclear. Chang (1997, Cell Biol. International, Vol. 21, pg 495-499) and Pain (1996, Development, Vol. 122, pg 2339-2348) taught PGCs were pluripotent and were capable of making chimeric chickens. It is unclear if EG cell colonies must have a different structure or function than PGCs. The specification states EG cell colonies are derived from PGCs (pg 9-10, Examples 1-2) but does not define and distinguish EG cell colonies and PGCs. The distinction between PGCs and EG cell colonies as claimed cannot be determined. It is unclear if the method is directed toward culturing PGCs that become EG cells or if a population of PGCs that contain EG cells are cultured so that EG cell colonies are obtained. Applicants have not addressed this rejection.

The metes and bounds of what applicants consider "EG cell characteristics" or an "EG phenotype" (claims 1 and 29, step c) cannot be determined. PGCs and EG cells

share characteristics. It cannot be determined if the phrases encompass any pluripotent cell because both PGCs and EG cells are pluripotent or if the phrase is limited to characteristics that are only found in EG cells. Applicants have not addressed this rejection.

The metes and bounds of products that are "differentiation inhibitory factors" used in the medium of claims 1 and 29, step a), b) and c)) remain indefinite for reasons of record. It remains unclear which, if any of the factors described in the specification (SCF, bFGF, IL-11, or IGF-I), are "differentiation inhibitory factors". Applicants have not addressed this rejection.

The metes and bounds of "germinal ridge stroma cells" (claims 5 and 29) remain unclear for reasons of record. It cannot be determined if any stromal cells from the gonad are encompassed by the phrase because such cells arise from the germinal ridge. It cannot be determined if the stromal cells must be isolated from an embryo at a particular stage. Therefore, it is unclear if the phrase limits the structure of the stromal cell or when the stromal cell is isolated. Applicants have not addressed this rejection.

Claim 9 remains indefinite for reasons of record because the metes and bounds of "units" of LIF is unclear. It cannot be determined by what standard the units are measured. Applicants' refer to "Appendix I, col. 1, "Performance Characteristics," but it is unclear to what this refers. The specification and the art at the time of filing did not define the standard "units" of LIF. Applicants have not addressed this rejection.

Claim Rejections - 35 USC § 102

Claims 1, 4-6, 8, 10, 11 and 13-15 remain rejected and claims 27-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Allioli (1994, Devel. Biol., Vol. 165, pg 30-37) for reasons of record.

Allioli taught isolating the gonads of stage 27-28 chicken embryos and culturing the cells therein in media. The cells included PGCs and fibroblasts. The fibroblasts created a feeder layer in culture and are "germinal ridge stroma cells" as claimed because they are isolated from gonads. The cells cultured were pluripotent. The media contained steel factor, LIF and FGF (pg 31, col. 2; 34, col. 2, "gonadal cell culture"; pg 36, col. 1, 2nd ¶), which are cells growth factors and differentiation inhibitory factors. Allioli taught culturing the PGCs in the same medium until colonies formed (pg 34, col. 2, 2nd full ¶ and last full ¶). This is the method used to make the feeder cells described in the specification.

Applicants argue Allioli did not teach long term culture and subculturing steps to culture the EG cells for a period of 7-10 days. Applicants' argument is not persuasive. The claims do not require long-term culture or culturing the cells for 7-10 days. Furthermore, Allioli taught culturing the cells for at least 4 days (pg 34, 1st full ¶), which applicants may consider a "long term culture." Small aggregates of cells were obtained (pg 34, col. 2, 2nd full ¶), which is equivalent to EG cell colonies as claimed. The cultures were subcultured (¶ bridging pg 34-35). Thus, Allioli meets all the limitations of the claims.

Claims 1, 4-11 and 13-15 remain rejected and claims 27-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang (1995, Cell Biol. Internatl. Vol. 19. No. 2, pg 143-149) for reasons of record.

Chang taught isolating stromal cells and PGCs from the genital ridge of day 5 (stage 27-28) chicken embryos. The cells were cultured in media containing 10% FBS, 10 ng/ml of IGF, 10 ng/ml FGF and 10 units/ml LIF (pg 144, col. 1). These cells inherently contain PGCs (pg 144, col. 1, ¶ 4; col. 2, 3 lines from the bottom; pg 146, Fig. 2, "PGCs derived from 5-day embryonic ridge in culture"). The PGCs of Chang are isolated from the gonad of an avian blastoderm and are pluripotent. The cell culture was maintained for at least 4 days (pg 14, col. 1, 3rd ¶, line 5).

Chang taught culturing the PGCs in the same medium until colonies formed (pg 145, col. 1, 9 lines from the bottom). The PGCs were recovered and subcultured for a period of time, which is equivalent to recovering and subulturing the established cell line.

Applicants argue Chang did not teach long term culture and subculturing steps. Applicants' argument is not persuasive. The claims do not require culturing the EG cell for more than 4 days as taught by Chang. Chang clearly taught subculturing the cells on pg 145, col. 1, 9 lines from the bottom).

Applicants argue subulturing PGCs with GR stroma cells as taught by Chang is not within the scope of the claims. Applicants' argument is not persuasive. Subculturing is in step c) of claims 1 and 29 and is generic to any feeder layer. Step c) of claims 1 and 29 does not exclude GR stroma cells from being part of the feeder layer.

Claims 1, 4-11 and 13-15 remain rejected and claims 27-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang (1997, Cell Biol. Internatl., Vol. 21, No. 8, pg 495-499) for reasons of record.

Chang taught isolating germinal ridge stromal cells from day 5 (stage 27-28) embryos. The cells were cultured for 5 days in media containing IGF, FGF and LIF with germinal ridge stromal feeder cells isolated from day 5 embryos to obtain gPGCs. The gPGCs were injected into recipient embryos and provided germline transmission (pg 496, "Materials and Methods"; pg 497, Fig. 1, "Progeny of germline chimeric chickens"). The gPGCs were recovered and subcultured for a period of time which is equivalent to recovering and subulturing the established cell line "in the same medium as in step a)" in step c). The gPGCs of Chang were EG cells as claimed because they provided germline transmission and were isolated from the germinal ridge of day 5 embryos.

Applicants argue it was well known that PGCs injected into recipient embryos are able to provide germline transmission. Applicants' argument is not persuasive. EG cells are capable of providing germline transmission (pg 14, Example 4). Therefore, the PGCs capable of providing germline transmission taught by Chang 1997, have the same structure and function as the EG cells described in Example 4. The PGCs described by Chang 1997 were simply named differently than the EG cells claimed.

Applicants argue Chang 1997 did not teach long term culture and subculturing steps. Applicants' argument is not persuasive. The claims do not require culturing the EG cell for more than 5 days as taught by Chang 1997.

Claims 1, 4-6, 8, 10, 11 and 13-15 remain rejected and claims 27-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Petitte (US Patent 6,333,192, filed 8-9-1999) for reasons of record.

The effective filing date of the claimed invention remains 2-11-2000, the filing date of PCT/KR00/00104, because 1999-4860, filed in Korea on 2-11-1999, did not teach isolating EG cells as claimed.

Petitte taught isolating PGCs and stromal cells from the gonads of stage 27-30 embryos. The cells were cultured in DMEM (col. 9, line 24-37, lines 49-55; claim 1). Petitte does not teach the avian fibroblasts were removed prior to adding the cells to STO feeder cells. Therefore, the culture of Petitte maintained for 5 days also has an avian fibroblast feeder cell matrix as claimed. The STO feeder cells can be replaced with avian fibroblast feeder cells (col. 5, line 64). LIF, IGF, FGF and SCF can be added to the media (col. 6, line 39). Thus, Petitte anticipates the claims.

Applicants reiterate their belief that claim 1 and Example 1 of the priority document indicate that PGCs are prepared in the first step that inherently comprise EG cells. Therefore, applicants conclude the claim has priority to 2-11-1999. Applicants' argument is not persuasive. The priority document does not teach that which is essential to the invention. In this case, the priority document does not teach or suggest that the PGCs comprised EG cells. It is not readily apparent that applicants suspected that the method described would result in EG cells (i.e. capable of making a germline chimera upon being introduced into a recipient embryo). The concept of EG cells

cannot be found in the priority document. Therefore, the effective filing date of the claimed invention is 2-11-2000.

Applicants argue the cells by Petitte are not established by long-term culture. Applicants' argument is not persuasive. The claims do not require "long-term culture."

Applicants argue Petitte did not teach obtaining pluripotent cells capable of producing a chimeric avian. Applicants' argument is not persuasive. The cells had an EG phenotype as claimed because they were pluripotent, undifferentiated and stained with anti-SSEA-1 antibody. The claims are not limited to obtaining EG cell capable of providing germline transmission.

Conclusion

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 571-272-0804.

The official fax number for this Group is (703) 872-9306.

Michael C. Wilson

MICHAEL WILSON
PRIMARY EXAMINER